

Breach Notification and 5010 Deadlines: Regulations Outline New Deadlines for Breach Notifications and 5010 Standards Testing

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Several 2009 federal regulations describe new requirements and compliance deadlines for this year, including breach notification reporting and testing 5010 transaction standards. HIM professionals should be aware of these due dates to ensure their organizations' compliance.

Breach Notification Reporting

The HITECH breach notification rules from the Office for Civil Rights (OCR) and the Federal Trade Commission (FTC) went into effect September 23 and September 24, respectively. However, both agencies provided a grace period for enforcement until February 22, 2010. That date is upon us.

Entities associated with personal health records that fall under the FTC rule should have completed all processes and training regarding breach avoidance, internal breach reporting and analysis, individual notification, and FTC reporting by February 22. Such entities also must consider related state requirements in any training and procedures development.

HIPAA covered entities likewise must complete their breach avoidance, internal breach reporting, risk analysis, individual notification, and other processes, policies, and procedures by February 22. This includes determining processes with business associates. They should also have completed workforce training.

The HIPAA-related rules were interim final rules, and it is unclear at this time whether OCR will publish a final rule before February 22. OCR could make changes in the breach notification requirements. The issue of "harm" appeared to be the most controversial issue.

The harm provision allows the entity to make its own determination of whether the breach is likely to result in harm to the affected consumers. If it determines that the breach does not pose a reasonable risk, it is not required to notify the breach victims. A number of consumer-related groups complained about the lack of definitive criteria. However, should the harm provision stand, entities must still document the event and their analysis of the potential risk.

HIPAA providers and health plans, as well as business associates, must also consider state laws and regulations in addition to the federal regulations and design procedures, policies, and training to reconcile these companion requirements.

Training Required for Compliance

Training will be vital to successful compliance since these rules affect an entity's entire workforce as well as those key employees responsible for risk analysis, decision making, and informing individuals of the breach and reporting breaches to the federal government.

Workforce members are now subject to individual liability should they violate the HIPAA privacy rule, and the penalties for privacy violations are more severe. This is part of the new enforcement rules developed under HITECH. HIPAA covered entities should use this opportunity to revisit the HIPAA privacy and security requirements and individual responsibilities.

HIPAA covered entities are also required to report their breach logs to OCR for 2009. These logs cover the period from September 23 through December 31, 2009, and are due in early March. A new log for 2010 should have been started on January 1, 2010.

Privacy Regulations to Come

Entities also should be watching for an interim final rule that was expected in late December addressing HITECH privacy-related requirements, including:

- Amended business associate requirements
- Restrictions on certain disclosures of health information (provider to health plan)
- Use of the minimum data set
- Prohibition on the sale of protected health information
- Access to certain information in electronic format
- Marketing with protected health information
- Fundraising with protected health information
- Stricter enforcement requirements (in addition to those effective November 30, 2009)

Join Colleagues at Capitol Hill Day

Join other HIM professionals at AHIMA's Capitol Hill Day on March 23, 2010, to visit with members of Congress and discuss key issues affecting electronic health records, health information quality, and the HIM profession at this crucial time.

Capitol Hill Day will be held in conjunction with AHIMA's Winter Team Talks and includes a policy briefing on March 22. Previous Hill Days have resulted in positive legislation, as evidenced by certain ARRA provisions.

All AHIMA members are invited to attend these events. AHIMA's goal is to contact all members of Congress. Registration is open until February 26, 2010. Information and registration materials can be found at www.ahima.org/dc/hillday.

All of these expected requirements will be subject to state regulation preemption like other HIPAA requirements.

Three HITECH privacy-related requirements have been in place since enactment on February 17, 2009:

- HIPAA regulations applied to individuals involved in wrongful disclosure
- Requirements that health information exchange organizations, regional health organizations, and other similar organizations are considered business associates of HIPAA covered entities
- Provision for periodic audits of covered entities and business associates

AHIMA offers resources to help address the HITECH breach requirements as well as the HIPAA privacy and security requirements. These materials are available on AHIMA's ARRA Web site, www.ahima.org/arra, and the AHIMA Body of Knowledge, www.ahima.org. Links to the full breach notification rules are also available on the ARRA site.

5010 Standards Testing

A January 2009 final rule from the Department of Health and Human Services mandated entities adopt and implement the new versions of the HIPAA transaction standards by January 1, 2012. However, it also mandated that entities internally test version 5010 by January 1, 2011, just 10 months away. This leaves covered entities the following year to test and finalize all necessary software changes with external partners by the compliance date of January 1, 2012.

On or after the January 1, 2012, health plans can refuse to accept claims and other transmissions in the old versions. Noncompliance could impede reimbursement and clog up the claims-processing pipeline.

It appears that many healthcare providers and vendors, along with some health plans, have not begun the process of upgrading their transaction software and necessary applications to meet the testing milestone. Reaching compliance by January 1, 2012, could be a problem for them (for more on this, read the "Data Standards" column "[Why 5010 Is Needed](#)" [...]).

The ICD-10 Connection

AHIMA has suggested that components of the preparation and implementation of the HIPAA transaction standards upgrades could be coordinated with the implementation of the ICD-10-CM/PCS classification systems, which have a compliance date of October 1, 2013.

While this implementation period is more than three years away, HIM professionals know that there are a number of interim changes that must be completed to reach this compliance date.

Wise implementers are moving forward now in concert with the transaction upgrades and other needs to make their implementations as effective and efficient as possible.

In hearings late in 2009 the Centers for Medicare and Medicaid Services reiterated that these compliance dates will not slip. Meeting these deadlines, especially those associated with the HIPAA transaction standards, requires a concerted effort among providers, vendors, clearinghouses, and trading partners, now.

Some in the industry have voiced concern that responding to the meaningful use criteria, which will be released sometime in the first half of 2010, will provide enough of a challenge, so the transaction and ICD-10-CM/PCS upgrades should wait.

While the criteria do need to be considered, the planning and implementation of these other requirements should not languish. Any health IT purchase, hardware or software, requires vendor readiness for the HIPAA transaction standards upgrade and ICD-10-CM/PCS, along with any other requirements that might come about through the meaningful use criteria.

Organizational readiness depends on HIM expertise and leadership. HIM professionals must take the lead on these issues in order to ensure organizational compliance.

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